



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, DC 20460

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OFFICE OF
ENVIRONMENTAL INFORMATION

MEMORANDUM

SUBJECT: Quality Staff Strategic Plan

FROM: Nancy W. Wentworth /s/ *Nancy Wentworth*
Director, Quality Staff (2811R)

TO: Margaret N. Schneider
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Office of Environmental Information (2810A)

I am pleased to release of the first-ever strategic plan for the Quality Staff. This Plan is the result of a planning process that took over two years to define not only the Quality Staff's mission and goals, but also our vision for the future and our core values. Most importantly, the Plan will serve as a framework for quality assurance planning and resource allocation decisions for the staff over the next five years.

Strategic planning is a continual process. The next steps for the Quality Staff will be to develop our Quality Assurance Annual Report and Work Plan for FY2001/2002 in addition to the other steps outlined in the Plan. I look forward to successful implementation of this Strategic Plan with the expectation that improving the performance of the Quality Staff will help to improve the Agency's Quality System.

Attachment

cc: Inspector General
Regional QA Managers
National Program Office QA Managers
ORD QA Managers



Quality Staff Strategic Plan

September 2001

FOREWORD

This is the initial Strategic Plan for EPA's Quality Staff. The Quality Staff is a small organization, located within EPA's Office of Environmental Information, that is responsible for overseeing the EPA's Quality System. This plan outlines the Quality Staff's mission and goals and serves as a framework for quality assurance planning and resource allocation decisions. This strategic plan includes the Staff's vision for the future of quality, its goals for the program, and its core values, along with the essential actions over the next 5 years which the Quality Staff believes are necessary for its goals to be achieved.

TABLE OF CONTENTS

	<u>Page</u>
1.0 INTRODUCTION	1
1.1 THE 2001 STRATEGIC PLAN FOR THE QUALITY STAFF	1
1.2 BACKGROUND	1
1.3 THE QUALITY STAFF	2
1.4 THE STRATEGIC PLANNING PROCESS	4
2.0 VISION, MISSION, AND GOALS	5
2.1 VISION FOR THE FUTURE OF QUALITY	5
2.2 THE QUALITY STAFF MISSION	5
2.3 THE QUALITY STAFF CORE VALUES	6
2.4 QUALITY STAFF'S GOALS	6
2.5 RELATIONSHIP TO EPA'S GOALS	7
2.6 RELATIONSHIP TO OEI'S OPERATING PRINCIPLES	8
3.0 STRATEGIC AREAS OF CONCENTRATION	11
3.1 OBJECTIVE 1: DOCUMENTING QUALITY SYSTEM POLICIES AND PROCEDURES	11
3.2 OBJECTIVE 2: MANAGING CHANGE	12
3.3 OBJECTIVE 3: INCREASING AGENCY MANAGEMENT AWARENESS OF QUALITY	13
3.4 OBJECTIVE 4: IMPROVE OUTREACH TO AND COLLABORATION WITH THE ENVIRONMENTAL COMMUNITY	14
3.5 OBJECTIVE 5: COMMUNICATING THE MESSAGE	15
3.6 OBJECTIVE 6: TRAINING	17
3.7 OBJECTIVE 7: QUALITY ASSESSMENT	18
3.8 OBJECTIVE 8: IMPROVING ORGANIZATIONAL STRENGTH IN THE QUALITY STAFF	20
4.0 NEXT STEPS	21
4.1 CONTINUING THE PROCESS OF STRATEGIC PLANNING	21
4.2 MEASURING PERFORMANCE	22
4.3 OTHER PLANNING EFFORTS	22
APPENDIX A. THE EPA QUALITY SYSTEM	A-1

1.0 INTRODUCTION

1.1 THE 2001 STRATEGIC PLAN FOR THE QUALITY STAFF

This is the initial Strategic Plan for the Environmental Protection Agency's (EPA) Quality Staff. The Quality Staff is a small organization, located within the Immediate Office of EPA's Office of Environmental Information, that oversees the Agency-wide Quality System. This plan outlines the Quality Staff's mission and goals, and serves as a framework for quality assurance planning and resource allocation decisions. This strategic plan includes the Staff's vision for the future of quality, its goals for the program, and its core values, along with the essential actions which the Quality Staff believes are necessary for its goals to be achieved. This plan will be reviewed annually and updated as needed.

It is important to note that this Strategic Plan is focused on the Quality Staff, not on the Agency-wide Quality System. Efforts to develop a strategic plan for the Agency-wide system are discussed below; these efforts will influence future versions of this plan. While a plan for the Agency-wide Quality System is important, it is necessary to have a strategic plan specifically for the Quality Staff in order to define priorities and goals for the organization.

1.2 BACKGROUND

The EPA has recognized the importance of environmental data and information in supporting its actions and decisions. The Agency formalized its quality assurance (QA) program in 1979, and since then, has substantially expanded the scope of the program from a focus on analytical quality control (QC) to a much broader quality systems approach that encompasses all aspects of the planning, collection, and use of environmental data and information.

In October 1999, EPA created a new Assistant Administratorship, called the Office of Environmental Information. Program leadership for the Agency's quality programs was assigned to this Office¹, with staff support being provided by the Quality Staff. EPA's individual Offices and Regions implement the Agency's quality program. Specific roles and responsibilities of the Quality Staff are described in Section 1.3; roles and responsibilities of organizations across EPA, along with a description of the Agency-wide Quality System, are contained in Appendix A.

Implementation of the Agency's quality system is evaluated by a number of organizations. The Quality Staff has an ongoing program in which they assess implementation of quality programs across

¹Prior to October 1999, leadership was assigned to the Office of Research and Development, with staff support being provided by the Quality Assurance Division in the National Center for Environmental Research and Quality Assurance.

the Agency. The Science Advisory Board and the Office of the Inspector General have also evaluated quality program implementation, including the Quality Staff's activities and those of other Agency organizations. The results of these evaluations indicate:

- Implementation of quality requirements is uneven across the Agency.
- Resources to conduct all required quality-related activities are not always provided.
- Staff and managers are often not adequately trained to carry out their assigned responsibilities.
- Oversight of subsidiary programs (Regional and State program implementation, contractors and assistance agreement holders) is incomplete.
- Staff with quality responsibilities do not have sufficient organizational independence to effectively carry out their assigned responsibilities.
- There are however a number of excellent programs being implemented.

While the weaknesses noted above are important, there are many successes in quality program implementation across the Agency. It is important that the successes be publicized so that others may learn and improve other programs.

1.3 THE QUALITY STAFF

The Quality Staff's activities cover activities that are implemented by organizations throughout the Agency. Responsibility for these activities comes to the Quality Staff through delegations of authority from the Assistant Administrator for Environmental Information and the organizational functional statement. The Quality Staff is responsible for:

- Establishing, documenting, and periodically revising Agency policies and procedures for planning, implementing, and assessing the effectiveness of the mandatory Agency-wide Quality System;
- Reviewing Quality Management Plans from Agency components conducting environmental programs for implementation for up to five years;
- Performing periodic management assessments of all EPA organizations conducting environmental programs to determine the effectiveness of their mandatory quality systems, and recommending corrective actions;
- Developing generic training programs, for all levels of EPA management and staff, so that quality management responsibilities and requirements are understood at every stage of project implementation;

- Providing communications and outreach to EPA QA Managers and personnel on relevant EPA Quality System issues;
- Representing EPA to other Federal organizations and quality professional organizations, and standards development organizations for quality management and quality assurance;
- Performing periodic assessments of all EPA organizations producing scientific and technical work products for use in Agency decisions, to determine their conformance with the Agency's Peer Review Policy; and
- Developing generic training programs, for all levels of EPA management and staff, so that peer review responsibilities and requirements are understood at every stage of scientific and technical product planning, development, and use.

These responsibilities put the Quality Staff at the forefront of the Agency's quality efforts for environment measurement and scientific/technical product development and use. A list of some of the products and services the Quality Staff provides is listed in Box 1.

Box 1: Quality Staff Products and Services	
<i>Products</i>	
✓	Guidance Documents
✓	Requirements Documents
✓	Policy Statements
✓	Federal Regulations
✓	Training Courses
✓	Annual Training Conference
✓	Annual Quality Management Conference
✓	Peer Review Product Tracking System
✓	Annual Report on the EPA Quality System
<i>Services</i>	
✓	Review and approval of Quality Management Plans
✓	Assessments of EPA's quality systems
✓	Assessments of EPA's peer review activities
✓	Training on quality management and peer review
✓	Review of Agency QA Annual Reports and Work Plans
✓	Representing EPA on quality management issues
✓	Conference calls for EPA QA community

The Quality Staff, led by a Director, consists of 16 full-time individuals and 2 support personnel. Because the work the Quality Staff works with the technical components of the Agency, the staff is primarily technical in nature, and includes biologists, chemists, statisticians, and other scientists.

The Quality Staff routinely works with staff from the National Program Offices, the Regions, and the Office of Research and Development. The Quality Staff considers its client community to include not only the internal Agency clients but its partners from other Federal Agencies, the States and the regulated community because consistent quality systems must permeate all the environmental programs, from the community environmental organizations to the Federal regulation writers.

1.4 THE STRATEGIC PLANNING PROCESS

The original motivation for developing a strategic plan for the Quality Staff was based on a recommendation from EPA's Inspector General. In 1998, the Inspector General recommended that:

To further institutionalize EPA's quality assurance program, require Quality Assurance Division to develop a strategic plan and annual performance plans including appropriate outcome-based performance measures and the level of resources needed.

This document contains the strategic plan for the Quality Staff and includes a component to develop annual performance plans for the staff's major activities.

This effort was part of a larger effort by the National Center for Environmental Research and Quality Assurance where the Quality Staff previously resided. This effort included:

- A customer survey to solicit input on current activities.
- A strategic planning meeting with the Director and a subset of members from the Quality Staff, to draft the mission, vision, and goals of the organization.
- Three all-hands strategic planning meetings to:
 - reach consensus on mission, vision, and goals;
 - to define and reach consensus on major activities; and
 - to define and reach consensus on the tasks relative to these activities.

Comments from outside sources, such as the Science Advisory Board, on program activities were incorporated into the planning process.

While the motivation was not internal, the entire staff recognized the importance of the initiative and actively participated in the development process. The Staff sees this plan as a method to improve both internal operations and the Agency-wide Quality System. Follow-up activities to the development of this Strategic Plan are described in Chapter 4.

2.0 VISION, MISSION, AND GOALS

2.1 VISION FOR THE FUTURE OF QUALITY

The programs for which the Quality Staff has development, management, and oversight responsibilities must be implemented by others for the Quality Staff's efforts to be successful. Therefore, the Quality Staff's vision for the future of quality in the Agency is more expansive than the Quality Staff's actions.

The Quality Staff's vision for the future is:

The environmental community uses appropriate quality practices to support environmental policies, decisions, and science so that:

- ★ *Quality is integral to all environmental operations,*
- ★ *Successes in quality implementation are common and are communicated across the Agency and to all interested parties, and*
- ★ *The environmental community welcomes and respects quality practices.*

2.2 THE QUALITY STAFF MISSION

The Quality Staff sees its mission in environmental protection as a cross-cutting one.

The Quality Staff's mission is to:

- ★ *lead in developing national policies and practices for quality systems for environmental programs and*
- ★ *ensure the environmental community has and consistently uses practices that provide appropriate data and information to support policies, decisions, and science.*

2.3 THE QUALITY STAFF CORE VALUES

The Quality Staff has a set of core values that are central to its operations both within and outside the Agency.

The Quality Staff believes:

- ★ *That quality concepts and practices are critical to all environmental policies, decisions, and science.*
- ★ *In providing leadership in developing Quality practices.*
- ★ *In the Scientific Method.*
- ★ *In the value of each person's expertise and contribution.*
- ★ *That our efforts benefit human health and the environment.*
- ★ *In treating others in a fair, unbiased, and balanced manner.*

2.4 QUALITY STAFF'S GOALS

The Quality Staff has identified 8 goals that must be achieved to address its vision for the future of quality. These goals are:

- ✓ *Documenting Quality System Policies and Procedures* – Ensuring that the Agency-wide Quality System is fully defined, up-to-date, relevant, and that methods for implementing the Quality System exist and are easily applied.
- ✓ *Managing Change* – Optimizing our influence in these areas and our response to change to further the Quality Staff's mission.
- ✓ *Increasing Agency Management Awareness of Quality* – Assisting Agency's management in embracing and supporting the quality system and providing guidance that facilitates the utilization of quality system components and tools in environmental decision-making.

- ✓ *Improve Outreach to and Collaboration with the Environmental Community* – Providing leadership in expanding Quality’s scope of appreciation and collaboration across the whole environmental community.
- ✓ *Communicating the Message* – Communicating quality successes so they may be internalized throughout the environmental community.
- ✓ *Training* – Ensuring that adequate fundamental Quality System training is available to all levels of EPA.
- ✓ *Quality Assessment* – Ensuring that the Agency’s quality systems and peer review programs promoting the quality of science are sufficient and appropriate to support environmental decision making.
- ✓ *Improving Organizational Strength in the Quality Staff* – Building a cohesive, efficiently operating work team supported with necessary resources and committed to the realization of our quality vision.

Essential actions which the Quality Staff believes are necessary for its goals to be achieved are described in Chapter 3.

2.5 RELATIONSHIP TO EPA’S GOALS

The mission of the EPA is *to protect human health and safeguard the natural environment— air, water, and land— upon which life depends*. The mission of the Quality Staff supports the Agency mission by ensuring that EPA uses data of adequate quality and quantity to make decisions regarding risks to human health and the environment. Without such support, the Agency would be unable to make decisions that are protective and defensible.

In the same manner, the work of the Quality Staff contributes to the achievement of EPA’s goals identified in the Agency’s strategic plan (Box 2). Since the collection and use of environmental data are integral to ensuring EPA

Box 2: EPA’S 10 GOALS

- ✓ Clean Air
- ✓ Clean and Safe Water
- ✓ Safe Food
- ✓ Preventing Pollution and Reducing Risk in Communities, Homes, Workplaces, and Ecosystems
- ✓ Better Waste Management, Restoration of Contaminated Waste Sites, and Emergency Response
- ✓ Reduction of Global and Cross-Border Environmental Risks
- ✓ Expansion of Americans’ Right to Know about the Environment
- ✓ Sound Science, Improved Understanding of Environmental Risk, and Greater Innovation to Address Environmental Problems
- ✓ A Credible Deterrent to Pollution and Greater Compliance with the Law
- ✓ Effective Management

obtains these goals, the work the Quality Staff performs in managing the Agency-wide Quality System provides a direct benefit to each goal.

2.6 RELATIONSHIP TO OEI'S OPERATING PRINCIPLES

Work performed by the Office of Environmental Information (OEI) is addressed in EPA's Goal 7, Quality Environmental Information:

Easy access to a wealth of information about the state of their local environmental will expand citizen involvement and give people tools to protect their families and their communities as they see fit. Increased information exchange between scientists, public health officials, businesses, citizens, and all levels of government will foster greater knowledge about the environment and what can be done to protect it.

OEI's vision in supporting the Agency mission and Goal 7 is to be *an innovative center of excellence that advances the creation, management, and use of information as a strategic resource, to enhance public health and the environment*. OEI established six (6) operating principles in concert with the OEI vision in its Year 2000 Action Plan. These principles are shown in Box 3. The OEI operating principles and completion of planned work projects allow OEI to meet its vision of advancing the creation, management, and use of information as a strategic resource.

Many of the OEI projects are directly aimed at improving the quality of information content, and improving the quality of collection, storage, exchange, manipulation, and access to Agency information. The Quality Staff, and the Agency-wide Quality System, play an integral role in the ability of OEI to successfully meet its goals. Specifically, through its role of managing the Agency-wide Quality system, the Quality Staff supports OEI's operating principles by providing methods to assist EPA in:

- Producing data of known and documented quality, and documenting activities and oversight for evaluation purposes. This reduces the potential for waste, fraud, and abuse. *(Enhance information quality)*
- Determining if data can be used for a specific purpose when the quality of data is known. This reduces the likelihood of losing challenges to regulations, enforcement actions, permit appeals, etc., resulting from the use of data of uncertain quality. *(Foster information-based decisions)*
- Reducing resource expenditures as EPA's information needs are more closely matched to the information collection activities. For example, through systematic planning, only

the appropriate type, amount, and quality of data will be collected by EPA, others collecting data on behalf of EPA, and others collecting data to satisfy EPA requirements. (*Burden reduction and information integration*)

Box 3: OEI's Operating Principles

- ***Integrate information:*** EPA has committed to integrating information as a key theme for the Office of Environmental Information. The long-term vision for EPA's integration effort is to create a network that supports core mission functions and to support a broad data exchange network with our State and Tribal partners and other environmental stakeholders.
- ***Enhance information quality:*** This principle focuses on the value of environmental information for all stakeholders by seeking customer feedback and systematically improving the information's usability, clarity, accuracy, reliability, and scientific defensibility. This includes instituting compatible data standards and ensuring that data are known and appropriate for intended uses. Enhanced information quality will enable a more accurate, comprehensive environmental "picture" for EPA partners and stakeholders.
- ***Foster information-based decisions:*** EPA recognizes the need to evaluate data for appropriateness for its intended uses and to analyze, communicate, and provide access to appropriate data and information so that all stakeholders can use the information for improved environmental decision-making.
- ***Burden reduction:*** Increasing the efficiency of information collection by reducing unnecessary cost and burden to EPA State, Tribes, stakeholders, and customers in collection and using information is another priority of OEI. The outcome will be more streamlines and more efficient information exchange between EPA, State, Tribes, and stakeholders.
- ***Expand American's right-to-know:*** Providing the public access to EPA's wealth of data and information resources supports EPA's mission and many of our stakeholders goals to protect public health and the environment. Increased public access supports citizens' understanding and involvement and enables them to make decisions that help protect families and their communities.
- ***Strengthen and secure EPA's information infrastructure:*** Strengthening and securing EPA's information infrastructure is fundamental to increasing the availability and accessibility of environmental information to customers and stakeholders. EPA will remain vigilant in maintaining a strong and secure infrastructure that is capable of supporting the Agency's strategic goals. EPA recognizes that a secure information infrastructure is essential to maintaining Congressional and public confidence in EPA's stewardship of environmental and regulatory information.

3.0 STRATEGIC AREAS OF CONCENTRATION

3.1 OBJECTIVE 1: DOCUMENTING QUALITY SYSTEM POLICIES AND PROCEDURES

To ensure that the Agency-wide Quality System is fully defined, up-to-date, relevant, and that methods for implementing the Quality System exist and are easily applied.

The goal of the Agency-wide Quality System is to ensure that environmental programs and decisions are supported by data of the type and quality needed and expected for their intended use, and that decisions involving environmental technology are supported by appropriate quality-assured engineering standards and practices. The Quality Staff is responsible for setting policy for the Agency-wide quality system and for developing procedures to assist in the implementation of these policies. As such the staff develops guidance, software, and other resources to document procedures for quality management.

Task 1: ***Document the Agency's Quality System policies.*** The Quality Staff develops policies regarding the EPA Quality System, including requirements for both EPA and non-EPA organizations, for developing and maintaining a quality system that supports the Agency-wide system. Activities under this task include developing an Agency-wide Quality Management Plan; issuing new, and revising existing, policy for quality management for EPA organizations as necessary; issuing new, and revising existing, quality management regulations in the Code of Federal Regulations; developing and issuing new "Requirements" documents that contain mandatory, minimum specifications or procedures for use by non-EPA organizations; and developing and implementing the policy portion of an Annual Policy and Guidance Work Plan.

Task 2: ***Provide guidance to existing environmental programs on implementing quality practices.*** The Quality Staff will develop and implement a process for providing guidance on procedures for effectively planning, implementing, documenting, and assessing quality management practices applied to Agency programs, and execute this process as needed. Activities under this task include developing and implementing Standard Operating Procedures for document development; developing and implementing the guidance portion of the Annual Policy and Guidance Work Plan that identifies documents to be addressed by the Quality Staff during the year including completing guidance in development, revising existing documents as external changes warrant, and developing new guidance as needs are identified through the Annual Work Plan.

- Task 3:** *Determine the core responsibilities of a QA Manager.* The duties of a QA Manager are extremely varied: Program Offices, Regions, Laboratories, and Headquarters all demand attention to the needs of their immediate office. There are, however, many commonalities that link together the Agency's QA Managers and that could be considered core responsibilities. An understanding by the general Quality community of "what it takes" to be a QA Manager would focus on the leadership aspects of the position.
- Task 4.** *Define the Quality Staff's role internally and externally to EPA.* Within the Office of Environmental Information, the Quality Staff will determine the actual and intended roles and responsibilities of the assigned organizations, identify those new areas having a Quality component, and ensure that these quality responsibilities are satisfied. For the external environmental community, the Quality Staff will announce its operating plan and vision and establish firmly a leadership role for all Quality issues.
- Task 5.** *Develop Approaches for Laboratory Quality Systems Improvement.* The Office of the Inspector General has raised the issue of the integrity of analytical data received and used by the Agency as a major management concern. The Quality Staff will lead an effort to better understand the policy needs for quality systems' documentation, implementation, and oversight. This effort will be undertaken in consultation with the Quality and Information Council's Quality Subcommittee.

3.2 OBJECTIVE 2: MANAGING CHANGE

To optimize our influence in these areas and use these opportunities to further the Quality Staff's mission.

The work of the Quality Staff is done under circumstances of continual change, usually in areas beyond its control. Accordingly, the goal is to optimize our influence in these areas and use these opportunities to further the Quality Staff mission. Activities to accomplish the goal include:

- Task 1:** *Assess recent changes that affect the Agency-wide Quality System.* The environmental community, the General Accounting Office, EPA's Inspector General, the Science Advisory Board, and national and international standards organizations are just a few organizations with activities that have direct effects on the Agency-wide Quality System. The Quality Staff will identify potential impacts in a timely manner and identify methods to incorporate potential changes. Activities under this task include developing and implementing an Annual Managing Change Work Plan to identify opportunities, define priorities for work, identify target delivery dates for products, and allocate resources.

Task 2: *Provide leadership introducing QA to new areas and programs.* New environmental issues and the regulatory initiatives devised by the Agency or Congress represent opportunities for the Quality Staff to promote the advantages of quality management. The Quality Staff Director and staff will provide leadership to, and participate in, task forces and workgroups on important issues and programs to incorporate quality assurance techniques early in the development process.

Task 3: *Brief new political appointees.* One inevitable change is the turnover in political appointees which is especially rapid during the change of administration. Changes of political appointees occur at other times as well and the career public servants that serve in an acting capacity need to be briefed also. Activities include development, annual updating, and presentation of briefing materials.

3.3 OBJECTIVE 3: INCREASING AGENCY MANAGEMENT AWARENESS OF QUALITY

To assist the Agency's management in embracing and supporting the quality system and provide guidance that facilitates the utilization of quality system components and tools in environmental decision-making.

Task 1: *Seek upper management endorsement of the quality program.* Support from upper management is critical to full implementation of the Quality System. This endorsement includes strong support for the Quality System and Agency-wide implementation, including senior Agency managers' approval of quality policy documents and training requirements for their program managers and QA staff. The Administrator and senior management must be routinely updated on the status of the Quality System.

Task 2: *Establish QA performance standards for program managers.* Senior Managers are responsible for the development of organizational Quality Management Plans, and the implementation of approved plans in decision making and information collection. QA-related performance standards will assist managers in evaluating their individual quality management practices and in planning continuous improvement efforts.

Task 3: *Complete and distribute the annual report.* The EPA Quality System Annual Reports will detail how quality-related activities support the organization, what actions have been taken, and what actions are being planned. These reports will address all components of the Quality System and include conclusions and information about significant achievements, problems, and consequences.

Task 4: ***Establish Agency-wide focus group for Metrics.*** The International System of Units, universally abbreviated SI, is the modern metric system of measurement. This is the dominant measurement system used in science and is becoming the dominant measurement system used in international commerce. Executive Order 12770 provides Presidential authority and direction for the use of the metric system of measurement by Federal Agencies and Departments. An Agency-wide focus group will facilitate the implementation of this Executive Order at EPA.

3.4 OBJECTIVE 4: IMPROVE OUTREACH TO AND COLLABORATION WITH THE ENVIRONMENTAL COMMUNITY

To provide leadership in expanding Quality's scope of appreciation and collaboration across the whole environmental community.

As an acknowledged leader in quality management for environmental programs, the Quality Staff has a responsibility to reach out to the environmental community to share quality management experience and expertise. Such outreach may take the form of technical assistance to address specific issues or questions. In addition, the Quality Staff may collaborate with other EPA organizations, other Federal organizations, States, and standards development organizations on new initiatives to improve QA and QC practices and procedures. The goal here is to improve the Quality Staff's opportunities and effectiveness for outreach and collaboration.

Task 1: ***Assess new opportunities for outreach.*** The Quality Staff will identify potential opportunities for outreach and identify methods to take advantage of these opportunities. This will be documented in an Annual Communications and Outreach Work Plan which will identify these opportunities and those in the following Tasks, define priorities for work, identify target delivery dates for products, and allocate resources.

Task 2: ***Provide technical assistance to existing environmental programs on implementing quality practices.*** The Quality Staff will develop and implement a process for providing technical assistance to EPA organizations to enable those organizations to more effectively plan, implement, and determine the effectiveness of quality management practices applied to Agency programs.

Task 3: ***Lead EPA participation in and collaboration with inter-Agency committees and other organizations (e.g., States, Tribes, private sector) on environmental quality.*** Other governmental and private sector organizations need quality in the implementation of their environmental programs. The Quality Staff is the focal point for

EPA efforts to foster best practices in quality management for such programs. Participation in committees and collaboration with other organizations provides opportunities for sharing information on QA and QC as applied to environmental programs.

- Task 4:** *Increase participation in national and international fora on quality issues.* Protection of human health and the environment is a global issue. The implementation of effective quality management is also global in scope. Solutions to quality-related problems may be found through dialog at the international as well as the national level. The Quality Staff participates in conferences, meetings, etc., at the national and international level to assure that expertise and experience in quality practices for environmental programs may be effectively transferred to the global user community.
- Task 5:** *Lead EPA participation in national and international standards development on quality systems.* The Quality Staff is recognized as the leader for EPA in standards development work on national and international consensus standards on quality and is a major partner in EPA's efforts to develop environmental management standards. The Quality Staff input and accomplishments have had significant influence on several current and emerging standards. The Quality Staff will continue its leadership role in standards development at the national and international level.
- Task 6:** *Collaborate with other EPA organizations to identify improvements to the EPA Quality System.* The Quality Staff should collaborate with the EPA QA community to identify the practical aspects of what does or does not work well in applying quality practices to environmental programs. This would include establishing routine processes for soliciting feedback from the Agency QA community on proposed quality initiatives, documents, training modules, and policies. Such processes would include peer input and review, and discussions in monthly conference calls.

3.5 OBJECTIVE 5: COMMUNICATING THE MESSAGE

To communicate quality successes so they may be internalized throughout the environmental community.

The Quality Staff should advance the integration of quality into environmental operations by continually improving the communication of issues in environmental quality management and the use of innovative techniques and practices in assessing environmental data quality.

- Task 1:** *Assess and develop new opportunities for improving communications.* The Quality Staff will identify potential, and develop new, opportunities for communication

and identify methods to take advantage of these opportunities. These will be documented in an Annual Communications and Outreach Work Plan along with priorities for work, target delivery dates for products, and resources allocations.

- Task 2:** ***Communicate and implement Agency quality management policies, requirements, and tools.*** The Quality Staff will ensure that the QA community (both EPA and otherwise) have access to relevant tools and other sources of information and are well-informed about EPA's internal policies and external requirements. Activities under this task include developing and implementing a communication strategy detailing the background and recent changes to the Quality System and how these changes affect different user communities, developing examples of QA techniques that have solved difficult problems, maintaining and expanding the Quality Staff Website, encouraging the Agency-wide use of systematic planning through the development and implementation of a communications strategy, and creating a series of Quality Fact Sheets.
- Task 3:** ***Take a prominent role in EPA and at national and international conferences and meetings.*** The Quality Staff will maintain the high profile established at the Annual Conference on Managing Environmental Quality Systems by leading the agenda for the opening segment of the conference and aggressively seeking the Quality Staff involvement with national and international conferences having connections to environmental Quality. The Quality Staff will also increase its visibility internal to EPA by identifying opportunities for presentations by the Quality Staff on the latest developments in quality management.
- Task 4:** ***Communication of Peer Review Activities.*** The Agency's Peer Review System and the role of the Quality Staff is frequently misunderstood by both managers and staff. The Quality Staff will continue monthly teleconferences with the peer review coordinators on status of implementation, the establishment of a discussion database, and reporting to General Accounting Office and Congress on Peer Review.
- Task 5:** ***Establish a strong relationship with the Quality and Information Council.*** The Quality and Information Council is composed of senior managers drawn from across the Agency, and each has a somewhat biased view of what the Quality Staff must do for their area of concern. Extreme care in clarity of communication must be taken to ensure the responsibilities and direction of the Quality Staff are kept in consonance with the views of the Quality Board. The Quality Staff must be ready to take an active role in supporting the recommendations of the Council through technical expertise.

Task 6: *Publicize awards and recognitions of QA staff in the Agency.* QA staff throughout the Agency often receive awards or are given recognition for their work in promoting good QA practices; these are, however, only acknowledged at the local level. The Quality Staff will publicize these achievements and encourage the adoption of such methods in other parts of the Agency. In addition, the Quality Staff will establish criteria for a Quality Practice Award for innovative practices at the project level rather than the overall manager level.

3.6 OBJECTIVE 6: TRAINING

To ensure that adequate fundamental Quality System training is available to all levels of EPA.

The role of the Quality Staff, as mandated by EPA Order 5360.1 A2, is to develop generic training programs for all levels of EPA management and staff so that quality management responsibilities and requirements are understood at every stage of project implementation. The staff provides tools, training materials, and input on training design and delivery to facilitate knowledge transfer. The goal of the program is to provide training resources that allow organizations to tailor materials to fit their needs and to provide a generic, structured training program that enhances the participant's knowledge and skills.

Task 1: *Assessment of Agency QA training needs.* The role of the Quality Staff is unique in the training arena in that the staff does not assess individual training needs. Our needs assessment is targeted specifically to the Quality professionals within the Agency and its primary purpose is to identify unmet training needs across the Agency. The activities under this task include performing targeted training needs assessments, the development of a Agency-wide Training Program, and the development of an Annual Quality Staff Training Work Plan that defines priorities for work, identifies target delivery dates for products, and allocates resources.

Task 2: *Provide training for the QA community.* The Quality Staff has expanded its role in developing generic training materials to include providing offerings of their courses as resources permit. This task also incorporates the training the Staff provides at both the National Meeting and the Summer Training Conference.

Task 3: *Develop and/or redesign training courses to support continuous improvement of the Agency's Quality System.* The Quality Staff develops training courses that are interdisciplinary, comprehensive, and integrated with the requirements of the EPA Quality System. The curriculum will consist of basic core courses that address the introductory level knowledge and skills of personnel with quality-related tasks. Other

courses in the curriculum will build upon the knowledge and skill levels of courses offered at the introductory level. This assures that the range of courses provided by the Quality Staff address quality-related skills on a progressive level (i.e. orientation, specific skill based training, refresher training). Activities in this task include improving existing training courses and designing new training courses to meet documented training needs.

Task 4: *Establish a process to assist EPA organizations in determining Quality training for all technical and administrative managers and staff.* Because of the diversity of organizational work processes across the Agency, it is not possible to recommend any single curriculum for all of EPA. At a minimum, each organization should determine basic quality training needs for each job function; what training materials exist, need to be modified, or developed; and the preferred training delivery methodology. Activities under this task include developing and implementing a comprehensive plan for monitoring and improving the training curriculum and the development of an curriculum evaluation process to assess how well curriculum goals are being achieved in terms of stakeholder expectations and objectives and knowledge acquisition and use.

Task 5. *Revise Peer Review Training to Conform to Revised Handbook.* The Peer Review Handbook was developed in 1998, and the Quality Staff prepared generic training material to be used across the Agency. The Handbook was revised in December 2000, and the training material must be revised to reflect the new information contained in the Handbook.

3.7 OBJECTIVE 7: QUALITY ASSESSMENT

To ensure that the Agency's quality systems and peer review programs promoting the quality of science are sufficient and appropriate to support environmental decision making.

The Quality Staff has been assigned oversight of the Agency-wide Quality System and Peer Review Program implementation. Oversight includes assessing the current status for conformance to Agency policies and requirements, and for recommending improvements to these programs.

Task 1. *Review Quality System Documentation from EPA Organizations.* The Quality Staff is responsible for reviewing and approving Quality Management Plans and reviewing and compiling the QA Annual Report and Work Plans submitted by EPA organizations. Activities under this task include developing and implementing an Annual

Quality Systems Documentation Work Plan for the current year that defines priorities for work, identifies target delivery dates for products, and allocates resources.

Task 2. *Perform Management Assessments of EPA Quality Systems and Organizations.*

The Quality Staff is required to review each EPA Organization to determine if the organization's Quality System conforms to EPA policies and requirements. Organizations are reviewed on a three-year cycle (approximately) which leads to 15 audits a year. Activities in this task include developing and implementing a Annual Quality Systems Audits Work Plan that defines priorities for work, identifies target delivery dates for products, and allocates resources.

Task 3. *Perform Peer Review Oversight of EPA Organizations.* The Quality Staff is required to assess the implementation of EPA's peer review policies to evaluate its completeness and effectiveness. The oversight that the Quality Staff performs on behalf of the Office of Research and Development includes oversight of the annual review process and the assessments of individual organizations. Activities in this task include developing and implementing an Annual Peer Review Oversight Work Plan and reporting process that identifies for the current year's activities including assessments to be completed by the Quality Staff during the year, oversight of peer review reporting by the other organizations and defines priorities for work, identifies target delivery dates, and allocates resources.

Task 4. *Develop performance criteria and expectations for the Agency-wide Quality System.* Bench marking quality system performance within the Agency is critical to measuring progress in achieving the goals of environmental programs. To be able to evaluate the effectiveness of the Agency-wide Quality System, meaningful performance criteria and expectations must be established as well as the measures necessary to determine that they have been met. Qualitative, and where possible quantitative, performance measures need to be established to determine existing levels of quality and identify changes in quality over time. The performance measures indicate the benefits of the Quality System and how well the current system supports environmental decisions and programs.

Task 5. *Plan for successful implementation of the oversight programs.* This task addresses the vision of the Quality Staff for quality to be integral to environmental activities, successes in implementation to be frequent and communicated, and quality practices to be welcomed and respected (paraphrased). It is likely that many of the assessments will soon begin to show compliance with our described criteria. Therefore, the Quality Staff will develop a strategy that will address the next steps after organizations (and the Quality Staff) have met Agency criteria and goals.

Task 6. ***Conduct Technical Systems Audits of All Agency Laboratories.*** The Quality Staff will provide leadership to the effort by developing the audit process and ensuring that the audits are completed in a timely fashion with appropriate documentation of findings. The majority of the technical staff that will participate in the audits will come from other Agency organizations.

3.8 OBJECTIVE 8: IMPROVING ORGANIZATIONAL STRENGTH IN THE QUALITY STAFF

To build a cohesive, efficiently operating work team supported with necessary resources and committed to the realization of our quality vision.

Task 1: ***Institutionalize a continuing process of strategic planning within the Quality Staff.*** The Quality Staff must look to the future needs of the Agency and the related Quality Staff needs. Strategic planning is planning for the long term as distinguished from planning for day-to-day operations. Accordingly, strategic planning need not be done frequently, but, to avoid forgetting it in the crush of deadlines, does need to be done at deliberate, regular intervals. Activities under this task include updating this Strategic Plan and the supporting documents described below. More information on this task is contained in Chapter 4.

Task 2. ***Develop/Review Operating Plans for key programs.*** Operating plans will be developed for key programs that correspond roughly to the sections of the strategic plan: Policy and Guidance, Managing Change, Communications and Outreach, Training, Quality Systems Documentation, Quality Systems Audits, Peer Review Oversight. When written, these plans will constitute a complete picture of the Quality Staff program that can be presented to those within and outside of the program. More information on this task is contained in Chapter 4.

Task 3: ***Develop annual business plan for the Quality Staff.*** The annual business plan will synthesize the resource components and steps of the operating plans (Task 2) and the annual work plans into a uniform, annual business plan for the Quality Staff. More information on this task is contained in Chapter 4.

Task 4: ***Increase opportunities for team building through weekly scheduled meetings, reports, and tracking.*** This task provides an opportunity for staff members to discuss program issues and involvement in order to improve internal operations. Activities under this task include weekly staff meetings, weekly reports for OEI Quality Staff members, and the development and implementation of a Quality Staff tracking system.

4.0 NEXT STEPS

4.1 CONTINUING THE PROCESS OF STRATEGIC PLANNING

The Quality Staff and its Director are committed to institutionalizing a continuing process of strategic planning. As strategic planning is planning for the long term as distinguished from planning for day-to-day operations, it need not be done frequently. The Quality Staff will use a system of alternating major and minor planning events at six-month intervals. The annual major planning event would be for annual strategic planning and developing the annual Work Plans and Business Plan. The smaller meeting would occur six months later to assess progress toward strategic goals and make fine tuning management decisions.

Supporting the Strategic Plan are several supporting documents including:

- Operating Plans for the Quality Staff's Key Components;
- Annual Work Plans to support the overarching Operating Plans;
- and an Annual Business Plan. These documents will be updated through the planning meetings.

Together, the Operating Plans will constitute a complete picture of the Quality Staff program and activities that can be presented to those within and outside of the program. There will be seven operating plans to cover the activities of the Quality Staff: Policy and Guidance; Managing Change; Communications and Outreach; Training; Quality Systems Documentation; Quality Systems Audits; and Peer Review Oversight. These programs correspond roughly to the sections of the strategic plan contained in Chapter 3.

Each Operating Plan will describe the program in detail and include:

- a description of purpose or goal;
- a description of the entire activity;
- standard operating procedures, checklists, template memoranda and reports to support the activity;
- the measures for success of the activity and how an assessment will be performed;
- the way in which corrective actions will be administered and followed up, with potential consequences of non-compliance and strategy to deal with the possibility (if appropriate);
- a tracking system for components of the activity.

Each Operating Plan will be supplemented on an annual basis by an Annual Work Plan. Using the tasks identified in Chapter 3 as a framework, Annual Work Plans will define priorities for work; identify

target delivery dates for products; and allocate resources for the upcoming year for that individual program. The Annual Work Plans will be combined into an Annual Business Plan. This will synthesize the resource components and steps of the operating plans, and work plans into a uniform business plan for the Quality Staff. The Annual Business Plan will include items such as products for the fiscal year; critical steps for completion; timelines for accomplishing general Quality Staff priorities; full time equivalents and funding requirements; and travel dollar needs.

4.2 MEASURING PERFORMANCE

Traditionally performance measures for both the Quality Staff and the EPA Quality System have not been formally developed. As a result of the Government Performance and Results Act, this is changing. The Quality Staff will develop performance measures for:

1. Programs and activities the Quality Staff conducts
2. Customer Services
3. Members of the staff

Development of these measures will be part of the development of the Operating Plans for the Quality Staff's major activities. These performance measures will then be documented in the individual operating plans, assessed annually, included as part of the Annual Work Plans and Business Plan, and tracked using the Quality Staff Tracking System. Results of these performance measures will be used in the performance assessments of individual Staff members and reported to management as part of the EPA Quality System Annual Report (see Section 3.3, Task 3, "Complete and distribute the annual report").

The development of performance measures that assess quality is not simple. Common measures are simple 'bean counts' which answer 'how many' questions but cannot address 'how well' the Quality System is doing. For example, one could use the number of assessments performed by the Quality Staff as a performance measure. However, this would not measure the quality of the assessments and determine whether these assessments actually benefit the Agency-wide Quality System. Similarly, a performance measure at the staff level would include the number of assessment reports completed within specified number of days. This again would not measure the quality of the performance by the individual in the overall assessment, only the ability to produce a written document.

4.3 OTHER PLANNING EFFORTS

This strategic plan is focused on the activities of the Quality Staff but there are other important efforts underway that may influence this strategic Plan. Three important activities include:

- **The Data and Information Quality Strategic Plan:** This effort is led by the Quality Subcommittee of EPA's Quality and Information Council. The Data and Information Quality Strategic Plan will identify where and how to optimize the Agency's environmental data systems to improve the overall quality of the data. This effort was started in Summer 2000 and involves performing an analysis of the quality management activity chain across the entire data lifecycle or flow of data within an environmental data system to identify problems that impact data usability. This will permit the development of necessary quality system advances at appropriate lifecycle stages to improve the quality and usability of end products. This also involves the assessment of the EPA Quality System for appropriate flexibility to accommodate the evolution of data, data systems and data collection innovations that are foreseeable over the next five to ten years; and developing a strategy to: 1) implement needed changes, 2) embed data quality considerations into all Agency business practices, and 3) continually measure performance/progress/effectiveness of the Data and Information Quality Strategic Plan across the Agency's environmental data systems.
- **Agency-wide Quality System Strategic Plan:** This effort will be lead by the Quality Staff using a team of individuals across the Agency. The Agency-wide Quality System Strategic Plan will describe the program's mission and goals, serve as a framework for quality assurance planning and resource allocation decisions, and provide Agency QA Managers and program staff the direction necessary to implement a cohesive Agency-wide program. The plan would establish national strategies for achieving quality assurance goals and objectives in the future. This effort is in the planning stages.
- **Performance measures for Quality System:** This effort will develop outcome and output metrics for EPA data quality assurance activities. According to Government Performance and Results Act parlance, data quality improvements are more readily categorized as "outputs" than "outcomes." However, it is possible to document how data quality improvements contribute to and/or facilitate environmental outcomes, and to frame this process to provide a basis for development of outcomes metrics. The first phase of this development effort is complete and consisted of a series of analyses of available performance information on the Agency's Quality System. Additional work linking available performance information to program outcomes will identify candidate measures for consideration by program measures.

As the Quality Staff oversees the Agency-wide Quality System, the output from these efforts may affect the activities of the staff. Therefore, the completion of these activities may have a direct effect on future revisions of this Strategic Plan.

APPENDIX A

THE EPA QUALITY SYSTEM

The EPA Quality System is the means by which an EPA organization manages the quality aspects of their operations in a systematic, organized manner. The EPA Quality System encompasses a variety of technical and administrative elements, including:

- policies and objectives,
- organizational authority,
- responsibilities,
- accountability, and
- procedures and practices,

in order to provide the framework for planning, implementing, and assessing work performed by an organization and for carrying out quality assurance and quality control activities.

The EPA Quality System encompasses both management and technical activities pertaining to the planning, implementation, and assessment of environmental programs within the Agency's mission and scope. The EPA Quality System applies to environmental programs that encompass:

- the collection, evaluation, and use of environmental data, and
- the design, construction, and operation of environmental technology.

The EPA Quality System applies uniformly to EPA organizations and to non-EPA organizations funded by EPA.

The goal of the Agency-wide Quality System is to ensure that EPA's environmental programs and decisions are supported by data of the type and quality needed and expected for their intended use, and that decisions involving environmental technology are supported by appropriate quality-assured engineering standards and practices. Successful implementation of the EPA Quality System leads to:

- scientific data integrity,
- reduced or justifiable resource expenditures,
- proper evaluation of internal and external activities,
- reliable and defensible decisions, and
- burden reduction.

Overall, implementation of the EPA Quality System will reduce the Agency's vulnerabilities in decision making and increase EPA's credibility by providing the ability to make reliable, cost-effective, and defensible decisions.

The EPA Quality System is composed of individual quality systems developed and implemented by the EPA Regions, National Program Offices, and the National Centers and Laboratories and non-EPA organizations. Overall, there are more than 40 EPA organizations that maintain quality systems. Specialized, highly-visible programs (for example, EPA's Great Lakes Program) also may have their own quality systems. There are 11 basic quality management requirements defined in EPA Order 5360.1 for all EPA organizations covered by the EPA Quality System. These requirements are to:

- ✓ Conform to the minimum specifications of ANSI/ASQC E4-1994;
- ✓ Identify a QA Manager and ensure the organizational independence of this QA Manager function from environmental data operations;
- ✓ Develop a Quality Management Plan and implement this plan following Agency approval;
- ✓ Provide sufficient resources to implement the quality system;
- ✓ Perform assessments of the effectiveness of the quality system at least annually and implement corrective actions based on assessment results in a timely manner;
- ✓ Submit an QA Annual Report and Work Plan for the organization that summarizes the previous year's activities and outlines the work proposed for the current year;
- ✓ Implement Agency-wide Quality System requirements in all applicable EPA-funded extramural agreements;
- ✓ Provide appropriate training for all levels of management and staff to assure that QA and QC responsibilities and requirements are understood at every stage of project implementation;
- ✓ Use a systematic planning approach to develop acceptance or performance criteria for all work covered by the EPA Quality System;
- ✓ Have approved QA Project Plans, or equivalent documents, for all applicable projects and tasks involving environmental data; and

- ✓ Assess existing data, when used to support Agency decisions or other secondary purposes, to verify that they are of sufficient quantity and adequate quality for their intended use.

Non-EPA organizations are required to develop quality systems to support their environmental programs funded by EPA. Organizations that may be affected by the EPA Quality System requirements include: other Federal departments and agencies; State, local, and Tribal governments; academic and other non-profit organizations; and commercial business enterprises. Quality management requirements are defined through the following Federal Acquisition Regulations:

- 48 CFR 46, “*Higher-level Contract Requirements*” – Contains requirements for contracts, work assignments, delivery orders, and task orders.
- 40 CFR 30, “*Grants and Agreements with Institutions of Higher Education, Hospitals and Other Non-Profit Organizations*” – Contains requirements for organizations identified in title.
- 40 CFR 31, “*Uniform Administrative Requirements for Grants and Cooperative Agreement to State and Local Governments*” – Contains requirements for grants and cooperative agreements to State, local, and Tribal Governments.
- 40 CFR 35, “*State and Local Assistance*” – Contains requirements for financial assistance agreements to State and local governments.

The regulations specify exactly what an organization must do to comply with EPA policy. For environmental programs funded by EPA but not covered by the Federal Acquisition Regulations, EPA negotiates quality management requirements with the organization performing the work. In addition, each EPA organization’s Quality Management Plan describes how the organization will interact with, and any additional requirements for, the organizations they fund.